Notice of Allowability	Application No.	Applicant(s)	
	10/774,147	RYU ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *1-5 and 15-24*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 05172004
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *12122005* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to polypeptides, classified in class 530, subclass 328.

II. Claims 6-7, drawn to antibody, classified in class 530, subclass 387.1.

III. Claims 8-12, drawn to nucleic acid, vector, host cell, method of making protein, classified in class 435, subclass 69.1.

IV. Claims 13-14, drawn to method of inducing expression of arachidonic acid in a target cell by introducing nucleic acid encoding the polypeptide of claim 1, classified in class 514, subclass 44.

V. Claims 15-16, drawn to method of inducing expression of arachidonic acid in a target cell by administration of the polypeptide of claim 1, classified in class 514, subclass 13.

VI. Claims 17-19, drawn to method of activating PLA_2, classified in class 514, subclass 13.

VII. Claims 20-21, drawn to method of producing superoxide in a target cell, classified in class 514, subclass 13.

VIII. Claims 22-24, drawn to method of causing movement of a target cell, classified in class 514, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

2. The polypeptide of group I is related to the antibody of group II by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in other, materially different processes from the production of antibody such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

3. The polypeptide of group I is related to the nucleic acid of group III by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

4. The polypeptide of Group I and method of use of the polynucleotide of Group IV are related because the polynucleotide to encodes the polypeptide. Clearly, however, the polypeptide is not required for the practice of the method of use of the

polynucleotide, nor are they disclosed as capable of use together. Thus, notwithstanding the relationship, the two inventions are patentably distinct.

5. The polypeptide of Group I and the methods of use of the polypeptide of Groups V-VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as any one of the three claimed processes.

6. The antibody of group II and the nucleic acid of group III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

7. The antibody of group II is related to the method of using the nucleic acid of group IV by virtue of the fact that the polypeptide is encoded by the DNA. The inventions are distinct, however, because, while the polypeptide is the cognate antigen necessary for the production of antibody, the nucleic acid is not used in the method of

use of the antibody and is not necessary for practice of said method. Therefore, the inventions are distinct.

8. The antibody of group II is related to the methods of using the polypeptide of groups V-VIII by virtue of the fact that the polypeptide is the cognate antigen necessary for the production of antibody. The inventions are distinct, however, because the polypeptide is not used in the method of use of the antibody and is not necessary for practice of said method. Therefore, the inventions are distinct.

9. The nucleic acid of Group III and the method of inducing expression of arachidonic acid in a target cell of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as production of recombinant polypeptide.

10. The DNA of group III is related to the methods of using the polypeptide of groups V-VIII by virtue of the fact that the polypeptide is encoded by the DNA. The inventions are distinct, however because the DNA is not used in any of the methods of use of the polypeptide and is not necessary for any of said methods. Therefore, the inventions are distinct.

11. The method of inducing expression of arachidonic acid in a target cell of Group IV and the methods of using the polypeptide of groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group IV and the methods of using the polypeptide of groups V-VIII do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. Because these groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification, restriction for examination purposes as indicated is proper.

12. The methods of using the polypeptide of groups V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of using the polypeptide of groups V-VIII do not require each other for their practice; have separate utilities; are physically, chemically and biologically different from each other; and are subject to separate manufacture and sale from each other. Because these groups have acquired separate status in the art as further evidenced by their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

13. In Groups I, II and V-VIII the presence of multiple polypeptide sequences and, in Groups III and IV, the presence of multiple polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary with regard to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Applicants are required under 35 U.S.C. 121 to elect a single SEQ ID No. for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicants are advised that a reply to this requirement must include an identification of SEQ ID NO: that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. This is not to be construed as an election of species, but rather an election between patentably distinct inventions. Evidence showing that the sequences are somehow related such that one search query could cover all of them might be effective to negate this requirement.

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. During a telephone conversation with Joseph Hyosuk Kim on November 24, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5. Attorney Kim further elected to prosecute SEQ ID Nos.: 30-35, since Examiner considered those sequences sufficiently similar to negate the undue burden of searching more than one sequence. Claims 6-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Claims 1-5 are directed to allowable products. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 15-24,

directed to processes of using the patentable products, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 15-24 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 6-14, not directed to the process of making or using the patentable product, will not be rejoined.

EXAMINER'S AMENDMENT

19. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Hyosuk Kim on November 24, 2005.

The application has been amended as follows:

Cancel claims 6-14 as drawn to nonelected inventions;

In claim 1, delete, "SEQ ID NO: 1 . . . SEQ ID NO: 29,".

20. The following is an examiner's statement of reasons for allowance: Baek et al. (Reference C23) teach the consensus sequence XKYX(P\V)M, of which SEQ ID NO: 31 is a species. It is well established that a genus does not anticipate all species within it, thus, SEQ ID NO: 31 is patentable over the reference. In addition, Baek et al. were

focused on the formation of inositol phosphates, not on expression of arachidonic acid, activation of PLA2, producing superoxide or causing movement of a target cell and, thus, do not disclose those properties for SEQ ID NO: 31. The other prior art neither teaches nor suggests the polypeptides having SEQ ID Nos.: 30 or 32-35 as peptides having lengths up to about 20 amino acids; thus they are patentable. The claimed methods of use are also patentable since the polypeptides are not taught and because it would not require undue experimentation to determine how to administer the polypeptide, the method claims are enabled.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Drawings

21. The drawings filed on February 05, 2004 are accepted by the examiner.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-

0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Wax
Primary Examiner
Art Unit 1653

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